REMARKS

As a preliminary matter, Applicants would like to thank the Examiner for the courtesy of the informal telephone conference conducted on 10/18/2006. Applicants respectfully request that the Examiner call the undersigned Attorney of Record prior to any action on the merits after entry of the attached amendments. As stated during the teleconference, Applicants believe all amended claims to be allowable over the art of record.

SUPPORT FOR AMENDMENT

Support for the amendment of claims **91**, **93**, **95**, **97**, **99**, and **101** may be found in Applicants' claims and specification as originally filed. Accordingly, no new matter has been introduced.

After entry of the instant Amendment and concurrently filed Request for Continued Examination, claims **91 - 102** remain pending in the application. Reconsideration and allowance of all pending claims **91 - 102** is respectfully requested.

35 U.S.C. §112

Claims **90-102** stand rejected under 35 U.S.C. §112 as comprising new subject matter. Specifically, the Examiner asserts that "the specification as originally filed does not provide support for 'wherein the antiviral activity of the composition is approximately 50 times greater than that of the alcohol component taken alone'". This rejection is rendered mute in view of Applicants' preceding amendment of claims **91**, **93**, **95**, **97**, **99**, and **101**. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

35 USC § 103(a)

Claims **91-92** stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Katz *et al.* (US 5,952,392) in view of Arquette *et al.* (WO 9920224). Further, claims **93-102** stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Katz *et al.* (US 5,952,392) in view of Arquette *et al.* (WO 9920224), and further in view of Katz (4,784,794) or Katz (5,070,107).

Applicants respectfully traverse these rejections. Applicants further submit that a *prima facie* case of obviousness has not been established.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP 2143. Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not in Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 91-92

The Examiner proposes that Katz *et al.* (U.S. 5,952,392) discloses long chain fatty acids, or monounsaturated long chain alcohols in their effective amounts with a physiologically compatible carrier are useful in a pharmaceutical composition for topical application, intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity. However, Katz *et al.* (U.S. 5,952,392) does not disclose, teach or otherwise describe salts of fatty acids in combination with monounsaturated alcohols (much less in combination with mixed esters) as recited in Applicants' claims. In fact, the Examiner admits this by stating "[t]he prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with long chain fatty acids salts, and fatty acid esters herein in a composition for treating virus-induced and inflammatory disease of skin and membranes".

The Examiner further proposes that Katz *et al.* (U.S. 5,952,392) discloses "compositions therein for use in treating viral infections comprise active ingredient or combination of compounds as the active ingredients selected from a group consisting of saturated aliphatic alcohols, mono-unsaturated aliphatic alcohols, mono-unsaturated aliphatic amides and aliphatic acids having a carbon chain length of 18-28 carbons, wherein the active ingredient is present in an amount of 0.1 to about 50% by weight of the final composition". Katz *et al.* (U.S. 5,952,392), taken either alone or in combination with any other reference of record, does not teach, disclose or otherwise suggest the use of salts of long chain fatty acids or fatty acid esters. Rather, Katz *et al.* (U.S. 5,952,392) discloses a combination of mono-unsaturated aliphatic amides and aliphatic acids for treating viral infections, neither of which are claimed or disclosed in the present invention.

The Examiner goes on to propose that Arquette *et al.* (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols and the instant fatty acid esters with a physiologically compatible carrier for topical applications. The Examiner notes that Arquette *et al.* (WO 9920224) discloses "fatty acids such as oleic acid, myristic acid etc are used as emollients in pharmaceutical products" at page 1, lines 24-29. Applicants are affirmatively unaware as to where, at page 1, lines 24-29, Arquette *et al.* (WO 9920224) references "pharmaceutical products". In fact, Arquette *et al.* (WO 9920224) at page 1, lines 24-29, discloses that "[F]atty acids which are used in **cosmetics formulations** generally include at least stearic acid, oleic acid, myristic acid and palmitic acid" (emphasis added). That notwithstanding, Arquette *et al.* (WO 9920224) does not disclose, teach or otherwise suggest salts of long chain fatty acids in combination with long chain alcohols as recited in Applicants' claims as amended.

The Examiner suggests "[I]t would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids herein in a pharmaceutical composition, in methods for treating virus-induced and inflammatory disease of skin and membranes". Notwithstanding Applicants' preceding arguments, the Examiner's rejection in the instant case fails to provide a reasoned motivation to combine the cited references; however, even if the references were to be combined, their combination still would not teach or suggest the use of mononunsaturated long chain alcohols and fatty acid salts, and mixed esters in a physiologically active pharmaceutical composition, as recited in all of Applicants' pending claims.

The Examiner then suggests that "[O]ne of ordinary skill in the art at the time the invention was made would have been motivated to employ the instant monounsaturated long chain alcohols in combination with the instant claimed fatty acid herein in a pharmaceutical composition". This statement is *non sequitur* to the extent that Applicants' present invention utilizes the combination of mononunsaturated long chain alcohols and fatty acid **salts**, and mixed esters in a physiologically active pharmaceutical composition. No fatty acids by themselves are claimed.

The Examiner then asserts that "since all active composition components monounsaturated long chain alcohols, and fatty acids [...] are known to [be] useful to treat virus-induced and inflammatory disease of skin and membranes according to Katz *et al.* (U.S. 5,952,392), it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose" , and then adds "at least additive therapeutic effects would have been reasonably expected". For this latter proposition, the Examiner cites *In re Kerkhoven*, 205 USPQ 1069 (CCPQ 1980). Applicants again assert that the present invention does *not* claim fatty acids, rather, it claims the combination of **salts of fatty acids** with long chain alcohols and mixed esters. Moreover, since there is no motivation to combine salts of fatty acids with long chain alcohols and mixed esters, as in the present invention, there can be no expectation of success. Therefore, the Examiner's statement regarding that expectation of additive therapeutic benefits being reasonably expected is misguided. Furthermore, Applicants remain affirmatively unaware as to where in *In re Kerkhoven* such a proposition has been stated. Applicants again request clarification on this point so that the record of prosecution may be rendered clear.

That notwithstanding, Applicants' respectfully disagree with the Examiner's rejections. Specifically, Applicants remind the Examiner that it is the *combination* of long chain monounsaturated alcohols and fatty acid salts as claimed in the present invention that create an unexpected, synergistic effect that cannot be deduced from any of the prior art references, either taken alone or in combination.

The Examiner goes on to suggest that "it would have been obvious to a person of ordinary skill in the art at the time of the invention to employ the salts of fatty acid in he composition taught by Katz *et al.* (5,952,392). Applicants respectfully submit that skilled artisans would not have been motivated to combine **salts** of fatty acids with monounsaturated long chain alcohols disclosed and claimed in Applicants' invention to achieve a substantially similar result. The combination of

the claimed salts of fatty acids with monounsaturated long chain alcohols produces an unexpected synergistic effect, which exceeds the discrete additive combination of the individual components. *See* 37 CFR §1.132 affidavits of Robert Kleiman and David Ashley.

To rebut this, the Examiner claims "[I]t has been well settled that pharmaceutically acceptable salts of the pharmaceutical compound are obvious over the pharmaceutical compound." Later, the Examiner cites MPEP §2143.02 for the same proposition. As Applicants have explained in its Response dated 04/25/2006, to the extent that MPEP §2143.02 relies on *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986) for this proposition, Applicants respectfully traverse. In *In re Merck*, the method of treating depression with amitriptyline (or the non-toxic salts thereof) was found obvious in light of prior art, comparing the claimed compound to a structurally similar psychotropic compound known to possess antidepressive properties, suggested by clinical testing of amitriptyline as an antidepressant. *See* MPEP §2143.02 (discussing *In re Merck & Co.*). In the case of Applicants' invention, there is no prior art which has suggested that long chain monounsaturated alcohols in combination with salts of fatty acids according to the present invention would possess antiviral effects. Therefore, the precedent of *In re Merck & Co.* is not applicable in this case.

Further, the Examiner states "the same fatty acid salts are deemed obvious over the same fatty acids taught by the cited prior art, having the same therapeutic effects and usefulness in treating virus-induced and inflammatory diseases of skin and membranes". Applicants respectfully traverse this rejection. The combination of the claimed salts of fatty acids with monounsaturated long chain alcohols produces an unexpected synergistic effect, which exceeds the discrete additive combination of the individual components.

The Examiner then proposes that "[I]t would have been obvious to a person of ordinary skill in the art at the time of invention to add instantly claimed fatty acid esters to the composition comprising monounsaturated long chain alcohols, and salts of fatty acids because Arquette *et al.* teaches that the instantly claimed fatty acid esters are known to be useful as emollients in pharmaceutical compositions". Applicants respectfully submit that this proposition is *non sequitur*. Applicants are affirmatively unaware as to how a skilled artisan would have been motivated to combine monounsaturated long chain alcohols and salts of fatty acids of the present invention with fatty acid esters simply because fatty acid esters are useful emollients in pharmaceutical compositions according to Arquette *et al.* Applicants submit that there is no

prior art which has suggested that long chain monounsaturated alcohols in combination with salts of fatty acids and fatty acid esters according to the present invention would possess antiviral effects.

The Examiner further proposes that skilled artisans would have been motivated to combine the claimed fatty acid esters and salts of fatty acids with monounsaturated long chain alcohols, because "fatty acids broadly or monounsaturated long chain alcohols broadly are known to be useful in pharmaceutical compositions for topical application [...] because these compounds have antiviral activity based on Katz *et al.*" Notwithstanding that Applicants are affirmatively unaware as to *which* Katz *et al.* reference the Examiner is referring to, Applicants submit that this argument is *non sequitur*. Applicants submit that there is no prior art which has suggested that long chain monounsaturated alcohols in combination with salts of fatty acids and fatty acid esters according to the present invention would possess antiviral effects.

Finally, the Examiner asserts that skilled artisans would have "reasonably expected that combining the instant fatty acid esters taught by Arquette *et al.* with the instant fatty alcohols, and salts of instant fatty acid in a pharmaceutical composition would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes because fatty acid esters are known to be used as an emollient in pharmaceutical composition". Applicants submit that there is no prior art which has suggested that long chain monounsaturated alcohols in combination with salts of fatty acids and fatty acid esters according to the present invention would possess antiviral effects. Therefore, where there is no suggestion there can be no motivation to combine.

To rebut this, the Examiner states that the skilled artisan would have "reasonably expected that the combination of the instant fatty acid esters taught by Arquette *et al.* with the instant fatty alcohols, and the salts of instant fatty acid in a pharmaceutical composition would have at least additive effects." However, because there is no motivation or suggestion to combine Arquette *et al.* with any other reference to practice Applicants' invention, there can be no reasonable expectation of success. Where no motivation to combine can be found, any expectation of success concerning the proposed combination may only be regarded as unreasonable at best. Accordingly, Applicants' amended claims should not be rejected under § 103(a). See, for example, *Akamai Technologies, Inc. v. Cable & Wireless Internet Services, Inc.*, 344 F.3d 1186 (Fed. Cir. 2003) (There must be some teaching, suggestion, or motivation to combine

references.); *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313 (Fed. Cir. 2002) (The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence.) (citing *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999)); *Carella v. Starlight Archery*, 804 F.2d 135 (Fed. Cir. 1986) (Obviousness cannot be established by combining teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting a combination.); *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984) (The fact that the prior art could be modified so as to produce the claimed invention is not a basis for an obviousness rejection, unless the prior art suggested the desirability of the modification.); and *Ex parte Walker*, 135 USPQ 195 (BOPA 1961) (A combination of teachings must be proposed and the art should contain some suggestion of the desirability of making the proposed combination.)

"With respect to core factual findings in a determination of patentability, [the Examiner] cannot simply reach conclusions based on [his/her] own understanding or experience – or on [his/her] assessment of what would be basic knowledge or common sense. Rather [the Examiner] must point to some concrete evidence in the record in support of these findings." *In Re Zurko*, 258 F.3d 1379 (2001). Accordingly, Applicants' pending claims may not properly be considered as obvious under § 103(a) in view of Katz *et al.* (U.S. 5,952,392) and Arquette *et al.* (WO 9920224).

Claims 93-102

Claims **93-102** stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Katz *et al.* (US 5,952,392) in view of Arquette *et al.* (WO 9920224), and further in view of Katz (4,784,794) or Katz (5,070,107).

Applicants hereby re-incorporate the discussion of Katz *et al.* (5,952,392) and Arquette *et al.* (WO 9920224) above.

The Examiner states that "Katz *et al.* (5,952,392) does not explicitly teach the effective amount of monounsaturated alcohol as from about 0.1 mg to about 2 gm per 50 kg of body weight". Applicants add that Katz *et al.* (5,952, 392) teach the combination of long chain monounsaturated alcohols in combination with salts of fatty acids and fatty acid esters according to the present invention.

The Examiner states that "Katz (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a

pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight". Applicants respectfully submit that the Katz reference (US 4,874,794) does not disclose use of **mono-unsaturated** alcohols in combination with salts of fatty acids as recited in Applicants' claims as amended.

The Examiner suggests that Katz (US 5,070,107) discloses "effective amounts of long chain fatty alcohols broadly (*e.g.* C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 01. mg to 2g/per 50kg of body weight"; however, this is not the case. Nowhere in Katz (US 5,070,107) is the composition of salts of long chain fatty acids in combination with monounsaturated alcohols (much less, in combination with mixed esters) disclosed, taught or otherwise suggested as recited in Applicants' claims as amended.

The Examiner proposes that skilled artisans "would have been motivated to optimize the effective amounts of instantly claimed long chain monounsaturated alcohols in the composition because Katz '794 and '107 teaches effective amounts of structurally similar long chain fatty alcohols active agents for treating viral infections and skin inflammations as 01.mg to 2g/per 50kg of body weight". Notwithstanding Applicants' arguments presented above, skilled artisans would not have been motivated to combine **salts** of fatty acids with monounsaturated long chain alcohols disclosed and claimed in Applicants' invention to achieve a substantially similar result.

The Examiner has also cited *In re Boesh*, 617 F.2d 272 (C.C.P.A. 1980) for the proposition that "it is well within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect". However, Applicants' respectfully point out that *In re Boesh*, 617 F.2d 272, 276 (C.C.P.A. 1980) goes on to state "[...] where the results of optimizing a variable, which was known to be result effective, are unexpectedly good". That is not the case here. With respect to the instant application, skilled artisans would not have been motivated to combine the salts of fatty acids with the long chain monounsaturated long chain alcohols disclosed and claimed in Applicants' invention to achieve a substantially similar result. The combination of the claimed fatty acid salts with the disclosed monounsaturated long chain alcohols produces an unexpected synergistic effect which exceeds the discrete additive combination of the individual components.

CONCLUSION

The remaining cited references (if any) have been reviewed and are not believed to affect the patentability of the claims as amended. Claims **91 - 102** are pending in the application. Consideration and allowance of all pending claims **91 - 102** is earnestly requested.

No amendment made herein was related to the statutory requirements of patentability unless expressly stated; rather any amendment not so identified may be considered as directed *inter alia* to clarification of the structure and/or function of the invention and Applicants' best mode for practicing the same. Additionally, no amendment made herein was presented for the purpose of narrowing the scope of any claim, unless Applicants have argued that such amendment was made to distinguish over a particular reference or combination of references. Furthermore, no election to pursue a particular line of argument was made herein at the expense of precluding or otherwise impeding Applicants from raising alternative lines of argument later during prosecution. Applicants' failure to affirmatively assert specific arguments is not intended to be construed as an admission to any particular point raised by the Examiner.

Should the Examiner have any questions regarding this Response and Amendment, or feel that a telephone call to the undersigned would be helpful to advance prosecution of this matter, the Examiner is invited to call the undersigned at the number given below.

Respectfully submitted,
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Date: 02/26/2006

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